REMARKS

In response to the objections and rejections raised by the Examiner in the May 7, 2002 Office Action, our comments follow. Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance or at least in better condition for appeal.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 7, 10-12, 16-18, 20-22, 24-26, 28-43 and 48 are pending in this application. Claims 7, 10-12, 16, 18, 20-22, 24-26, 28-43 and 48 have been amended; claims 13, 14 and 44-47 have been cancelled. Support for the amended claims is found throughout the specification and from the claims as filed. No new matter is added by this amendment.

The objection to claim 16 for failing to end in a period has been overcome by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicant is entitled. Further, changes to the claims herein are not narrowing amendments. Accordingly, no estoppel as to equivalents arises from or is intended by this paper.

II. THE REJECTION UNDER 35 U.S.C. §112, 2nd PARAGRAPH, IS OVERCOME

Claims 13 and 14 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. These claims have been cancelled by this amendment, obviating the rejection.

III. THE REJECTION UNDER 35 U.S.C. §112, 1ST PARAGRAPH, IS OVERCOME

Claims 7, 10-14, 16-18, 20-22, 24-26 and 28-48 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The claims have been amended to clarify the nature of the nucleic acids and sets of nucleic acids recited in the claims.

The Office Action contends that the breadth of the claims is not supported by the specification because the claims encompass nucleic acids that are longer or shorter than those represented by SEQ ID NO:1-10. Applicants claim a broad genus, however, there is more than adequate support for the claims. To support a claim to a genus requires:

"sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of **relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure,** or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." (emphasis added) MPEP 2163 IIA3(a)ii.

Applicants have clearly provided relevant, identifying characteristics in the form of nucleotide sequences. Further, they have provided examples in the application and in the Declaration of Dr. Kornelia Berghof demonstrating the functional properties of the nucleic acid molecules and a correlation between function and structure. There are reasonable limits regarding what the claimed nucleic acid molecules can comprise. The fact that they are not necessarily required to comprise the entire disclosed sequence does not render them inadequately described.

Furthermore, limiting the Applicants to only the disclosed sequences would unfairly narrow the scope of the invention. For example, other parties could use nucleic acid molecules that comprise, but contain 20 nucleotides more than, SEQ ID NO:2 and 7 to practice this very invention, and they would fall outside the literal scope of the claims. Such a consequence is obviously contrary to the intended function of the patenting system.

One skilled in the art could clearly conclude from the application that the Applicants had possession of the claimed invention at the time of filing. Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are in order, and such relief is requested.

IV. THE REJECTION UNDER 35 U.S.C. §103 IS OVERCOME

Claims 7, 10-14, 16-18, 20-22, 24-26 and 28-48 were rejected under 35 U. S. C. §103(a) as being unpatentable over Holmes et al. (WO 95/00664). The rejection is traversed.

The Examiner alleges that Holmes teaches an invention which provides nucleic acid molecules for the detection and identification of *Salmonella* species, and for detecting one or more *Salmonella* serotypes and to kits comprising these nucleic acid molecules. However, none of the primer pairs according to Holmes enable the detection of all the representatives of the 7 *Salmonella* subspecies. For example, the ST11/ST15 primers fail to detect a number of

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

7. (Four Times Amended) A set of isolated nucleic acid molecules, wherein each member of the set comprises[comprising] at least 10 contiguous nucleotides of a sequence represented by[from a nucleic acid sequence selected from the group consisting of] SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, or[and] SEQ ID NO: 10 or[and] the complement of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, or[and] SEQ ID NO: 10, wherein the set consists essentially of one or more of said members, and wherein the set is used in nucleic acid hybridisation or amplification to detect[said 10 contiguous nucleotides are 100% or at least 80% identical to a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 10 and the complement of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 10 and said nucleic acid sequences allows the detection of] all representatives of *Salmonella enterica* subsp. *enterica, salamae, arizonae, diarizonae, houtenae, bongori* and *indica*[by means of nucleic acid hybridisation or amplification].

10. (Four Times Amended) The set of isolated nucleic acid molecules according to claim 7, wherein each [nucleotide] sequence contains 10 to 250 nucleotides.

11. (Thrice Amended) The set of isolated nucleic acid molecules according to claim 7, wherein each member of the set is single-stranded or has a complementary strand.

12. (Four Times Amended) The set of isolated nucleic acid molecules according to claim 7, wherein the[said isolated nucleic acid] sequence is present

(i) as DNA, or

(ii) as RNA corresponding to (i), or

(iii) as PNA.

16. (Thrice Amended) The kit according to claim 48[43], wherein the [set of] isolated nucleic acid molecules were[was] produced synthetically and in at least two separate synthesis batches.

24. (Twice Amended) The set of isolated nucleic acid molecules according to claim 7, wherein one or more members of the set is[said isolated nucleic acid molecules are] modified or

representatives of subsp. *arizonae*, and the ST11/ST14 primers fail to detect a number of representatives of subsp. *enterica*.

The Examiner is respectfully reminded that "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). Also, the Examiner is respectfully reminded that for the §103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow,* 5 U.S.P.Q.2d 1529, 1531 (Fed.Cir. 1988). If, as asserted on page 9 of the present Office Action, "the state of the art was very high at the time the invention was filed" and "[a] large number of references were available...that taught the ordinary artisan how to align sequences of bacteria to determine regions of similarity and variability", it would seem as though there would be a number of references that anticipated the instant invention. There are none. In addition, there is only one reference cited against the present application under Section 103, and that reference makes no claim or suggestion that it can reliably detect all the representatives of the 7 *Salmonella* subspecies, or even that it is possible. Success is found only in the instant application.

The cited document, in other words, does not lead a skilled artisan to practice the instant invention, or even teach or suggest that it will be successful. In view of these arguments, reconsideration and withdrawal of the Section 103 rejection are requested.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. Alternatively, consideration and entry of this paper is requested, as it places this application into better condition for purposes of appeal. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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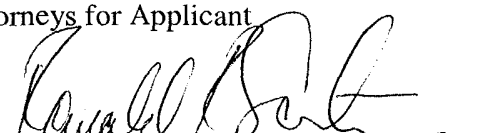
By: 

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labelled[nucleic acid molecule in which up to 20% of the nucleotides of at least 10 successive nucleotides of its nucleotide chain are nucleotides that do not occur naturally in bacteria].

25. (Twice Amended) The set of isolated nucleic acid molecules according to claim 24[14], wherein one or more members of the set [said isolated nucleic acid molecules]are modified or labelled [or additionally modified or labelled nucleic acid molecule that comprises, in a manner known *per se* for analytical detection processes,]with one or more radioactive groups, coloured groups, fluorescent groups, groups for immobilisation on a solid phase, or groups for an indirect or direct enzyme reaction.

26. (Twice Amended) The set of isolated nucleic acid molecules according to claim 7, wherein said isolated nucleic acid molecules are modified or labelled[or additionally modified or labelled nucleic acid molecule that comprises, in a manner known *per se* for analytical detection processes,]with one or more radioactive groups, coloured groups, fluorescent groups, groups for immobilisation on a solid phase, or groups for an indirect or direct reaction using antibodies, antigens, enzymes or substances having an affinity for enzymes or enzyme complexes.

28. (Amended) A set of isolated nucleic acid molecules, wherein each member of the set comprises[comprising] at least 10 contiguous nucleotides of a sequence represented by[from a nucleic acid sequence selected from the group consisting of] SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO:9 or[and] SEQ ID NO: 10 or[and] the complement of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO:9 or[and] SEQ ID NO: 10, wherein the set consists essentially of one or more of said members, and wherein the set is used in nucleic acid hybridisation or amplification to detect[said 10 contiguous nucleotides are 100% or at least 80% identical to a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO:9 and SEQ ID NO: 10 and the complement of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO:9 and SEQ ID NO: 10 and said nucleic acid sequences allows the detection of] all representatives of *Salmonella enterica* subsp. *enterica, salamae, arizonae, diarizonae, houtenae, bongori* and *indica*[by means of nucleic acid hybridisation or amplification].

29. (Amended) The set of isolated nucleic acid molecules according to claim 28, wherein each [nucleic acid] sequence contains 10 to 250 nucleotides.

30. (Amended) The set of isolated nucleic acid molecules according to claim 28, wherein each [nucleic acid] sequence contains 15 to 30 nucleotides.

31. (Amended) The set of isolated nucleic acid molecules according to claim 28, wherein each member of the set[isolated nucleic acid molecule] is single-stranded or has a complementary strand.

32. (Amended) A set of isolated nucleic acid molecules, wherein each member of the set comprises[comprising] at least 10 contiguous nucleotides of a sequence represented by[from a nucleic acid sequence selected from the group consisting of] SEQ ID NO:2[3], SEQ ID NO: 4, SEQ ID NO: 5, [SEQ ID NO: 6,] SEQ ID NO: 7, SEQ ID NO: 8[, SEQ ID NO: 9 and] or SEQ ID NO: 10 or[and] the complement of SEQ ID NO:2[3], SEQ ID NO: 4, SEQ ID NO: 5, [SEQ ID NO: 6,] SEQ ID NO: 7, SEQ ID NO: 8[, SEQ ID NO: 9 and] or SEQ ID NO: 10[and], wherein the set consists essentially of one or more of said members, and wherein the set is used in nucleic acid hybridisation or amplification to detect[said 10 contiguous nucleotides are at 100% or at least 80% homologous to a nucleic acid sequence selected from the group consisting SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9 and SEQ ID NO: 10 and the complement of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9 and SEQ ID NO: 10 and said nucleic acid sequences allows the detection of] all representatives of *Salmonella enterica* subsp. *enterica, salamae, arizonae, diarizonae, houtenae, bongori and indica*[by means of nucleic acid hybridisation or amplification].

33. (Amended) The set of isolated nucleic acid molecules according to claim 32, wherein each [nucleic acid] sequence contains 10 to 250 nucleotides.

34. (Amended) The set of isolated nucleic acid molecules according to claim 32, wherein each [nucleic acid] sequence contains 15 to 30 nucleotides.

35. (Amended) The set of isolated nucleic acid molecules according to claim 32, wherein each member of the set[isolated nucleic acid molecule] is single-stranded or has a complementary strand.

36. (Amended) A set of isolated nucleic acid molecules [comprising at least 10 contiguous nucleotides from a nucleic acid sequence selected from the group] consisting essentially of one or more of the sequences represented by SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO:9 or[and] SEQ ID NO: 10 or[and] the complement of SEQ ID NO: 1, SEQ ID NO: 2,

SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO:9 or[and] SEQ ID NO: 10, wherein the set is used in nucleic acid hybridisation or amplification to detect all representatives of *Salmonella enterica* subsp. *enterica, salamae, arizonae, diarizonae, houtenae, bongori* and *indica*[said 10 contiguous nucleotides are identical to said set of isolated nucleic acid molecules].

37. (Amended) The set of isolated nucleic acid molecules according to claim 36, wherein each [nucleic acid] sequence contains 10 to 250 nucleotides.

38. (Amended) The set of isolated nucleic acid molecules according to claim 36, wherein each [nucleic acid] sequence contains 15 to 30 nucleotides.

39. (Amended) The set of isolated nucleic acid molecules according to claim 36, wherein each member of the set[isolated nucleic acid molecule] is single-stranded or has a complementary strand.

40. (Amended) A set of isolated nucleic acid molecules [comprising at least 10 contiguous nucleotides from a nucleic acid sequence selected from the group] consisting essentially of one or more of the sequences represented by [SEQ ID NO: 1,] SEQ ID NO: 2, [SEQ ID NO: 3,] SEQ ID NO: 4, SEQ ID NO: 5, [SEQ ID NO: 6,] SEQ ID NO: 7, SEQ ID NO: 8[, SEQ ID NO:9] or[and] SEQ ID NO: 10 or[and] the complement of [SEQ ID NO: 1,] SEQ ID NO: 2, [SEQ ID NO: 3,] SEQ ID NO: 4, SEQ ID NO: 5, [SEQ ID NO: 6,] SEQ ID NO: 7, SEQ ID NO: 8[, SEQ ID NO:9] or[and] SEQ ID NO: 10, wherein the set is used in nucleic acid hybridisation or amplification to detect all representatives of *Salmonella enterica* subsp. *enterica, salamae, arizonae, diarizonae, houtenae, bongori* and *indica*[said 10 contiguous nucleotides differ from said set of isolated nucleic acid molecules in not more than one nucleotide].

41. (Amended) The set of isolated nucleic acid molecules according to claim 40, wherein each [nucleic acid] sequence contains 10 to 250 nucleotides.

42. (Amended) The set of isolated nucleic acid molecules according to claim 40, wherein each [nucleic acid] sequence contains 15 to 30 nucleotides.

43. (Amended) The set of isolated nucleic acid molecules according to claim 40, wherein each member of the set[isolated nucleic acid molecule] is single-stranded or has a complementary strand.

48. (Amended) A kit comprising: (i) one or more isolated nucleic acid molecules selected from the group consisting of [a set of isolated nucleic acid molecules comprising a

nucleic acid sequence selected from the group consisting of] SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO:9 and SEQ ID NO: 10 and the complement of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO:9 and SEQ ID NO: 10, and (ii) optionally substances for analytical detection processes.